

**ICCVAM**

Interagency Coordinating  
Committee on the Validation  
of Alternative Methods

**NICEATM**

National Toxicology Program  
Interagency Center for the Evaluation of  
Alternative Toxicological Methods

# ICCVAM Ocular Expert Panel Public Meeting

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National Institutes of Health  
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ICCVAM/NICEATM



# Welcome

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## Expert Panel Meeting to Assess the Current Validation Status of *In Vitro* Testing Methods for Identifying Potential Ocular Irritants

- ▶ US Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)
- ▶ NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)

# Composition of Expert Panel

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- ▶ **International Experts**
  - ▶ Europe, Japan, Canada, and the United States
  - ▶ From various organizations, e.g.,
    - ▶ industry, academia, government, animal advocacy groups, etc.
  - ▶ Representing themselves as individual scientists
  - ▶ Variety of scientific expertise in:
    - ▶ Toxicology
    - ▶ Human and veterinary ophthalmology
    - ▶ Biostatistics
    - ▶ Pharmacology
    - ▶ Anatomy and Physiology
    - ▶ Laboratory animal medicine
    - ▶ Pathology



# Importance of Science-Based Expert Panel Recommendations

- ▶ Advice of the Expert Panel regarding the validation status of the *in vitro* ocular test methods of interest, including their usefulness and limitations, will help guide:
  - ▶ the formulation of ICCVAM/NICEATM recommendations regarding the validation status of the 4 *in vitro* ocular test methods of interest
  - ▶ the conduct of any future studies that might be warranted that could help them satisfy ICCVAM's criteria for validation and acceptance of toxicological test methods and render any of these methods more acceptable for regulatory purposes
  - ▶ regulatory agencies on the use of data generated by these test methods that could help in their regulatory decision-making processes

# Regulation of Food, Drugs and Cosmetics in the United States

- ▶ FDA is charged with protecting American consumers by enforcing the *Federal Food, Drug, and Cosmetic Act*, its amendments, and several related public health laws
- ▶ Today's regulations grew out of a series of horrific and unfortunate health-related tragedies that caught the public's attention beginning in the early 1900's
- ▶ FD&C regulations have since come to address
  - ▶ demonstration of the safety and efficacy of regulated products
  - ▶ pre-market approval of all new drugs
  - ▶ coverage of cosmetics and medical devices
  - ▶ oversight of product labeling
  - ▶ quality, identity standards, and safety for foods and food additives
  - ▶ prohibition of false therapeutic claims for drugs
  - ▶ expansion of FDA's enforcement authority—
    - ▶ authorization to conduct factory inspections and impose injunctions
  - ▶ post-marketing surveillance



# The Lash-Lure Tragedy (c. 1930)

The Ad read:  
*The New and Improved  
Eye Brow and  
Eye Lash Dye  
**Lash Lure**  
Radiates Personality*

The Actual Effects:  
—Allergic reactions  
—Severe pain  
—Blindness  
—Death



# Ocular Irritancy Testing

- ▶ **The Draize eye irritancy test**
  - ▶ used since 1944
  - ▶ has provided important and useful information for eye safety assessments
- ▶ **Effort has since been invested in**
  - ▶ refining the test
  - ▶ reducing the number of animals used
  - ▶ searching for ways to replace the test with alternative non-animal methods
- ▶ **Considerations:**
  - ▶ human health and safety
  - ▶ scientific factors
  - ▶ animal welfare
  - ▶ economic and world trade implications
- ▶ **ICCVAM/NICEATM, in its efforts to respond to these issues of concern, has assembled this Ocular Expert Panel**